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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KATHERINE M. BURNETT and ELLEN S. KURTZ

Appeal 2009-012275
Application 10/722,134
Technology Center 1600

Decided: May 18, 2010

Before ERIC GRIMES, DONALD E. ADAMS and LORA M. GREEN,
Administrative Patent Judges.

GREEN, *Administrative Patent Judge.*

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's rejection of claims 39-42, 44-72, and 74-84. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

Claim 39 is representative of the claims on appeal, and reads as follows:

39. An anhydrous composition formulated for topical delivery comprising:
(a) about 1 to about 50 percent by weight of ethanol,
(b) propylene glycol,
(c) polyethylene glycol,
(d) glycerin, and
(e) ketoconazole,
wherein the composition is formulated as an anhydrous gel and does not contain a retinoid or a steroid.

The Examiner relies on the following evidence:

Sun	US 5,993,787	Nov. 30, 1999
Kabara	US 5,208,257	May 4, 1993
Thornfeldt	US 5,231,087	Jul. 27, 1993
Cauwenbergh	US 5,476,852	Dec. 19, 1995
Wang	US 5,110,809	May 5, 1992
Papa	US 4,214,000	Jul. 22, 1980
McCrea	US 5,292,530	Mar. 8, 1994

Appellants rely on the following evidence:

Declaration of Geert Cauwenbergh executed November 20, 2006.

The following grounds of rejection are before us for review:

- I. Claim 84 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description rejection.
- II. Claims 39-42, 44-62, 64, 66-71, 74, 75, 77-80, and 83 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by Sun.

- III. Claims 63, 65, and 72 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Sun and Kabara.
- IV. Claims 76, 81, and 82 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Sun and Thornfeldt.
- V. Claims 39-42, 44-51, 55-61, 63, 65-71, and 84 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Cauwenbergh and Wang.
- VI. Claims 62 and 64 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Cauwenbergh and Wang as further combined with Papa.
- VII. Claims 52-54 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Cauwenbergh and Wang, as further combined with McCrea.
- VIII. Claims 72 stands rejected under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Cauwenbergh and Wang, as further combined with Papa and McCrea.
- IX. Claims 74-83 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Cauwenbergh and Wang, as further combined with Thornfeldt.
- X. Claims 39-42, 44-72, and 84 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 8-16, 22, 25, and 26 of U.S. Patent No. 6,238,683.
- XI. Claims 74-83 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over

claims 1-3, 8-16, 22, and 24-26 of U.S. Patent No. 6,238,683 as combined with Thornfeldt.

- XII. Claims 39-42, 44-72, and 74-84 stand provisionally rejected under the judicially created obviousness-type double patenting as being unpatentable over claims 48-53, 56-62, and 86-118 of copending Application No. 09/562,376.

As Appellants do not argue the merits of rejections I, X, XI, and XII, we summarily affirm those rejections.

We affirm rejections II, III, and IV. As we are affirming rejections I, II, III, and IV, and as those rejections cover all of the claims on appeal, we vacate rejections V-IX.

ISSUES

Does the preponderance of evidence of record support the Examiner's conclusion that Sun renders the anhydrous composition of claim 39 obvious?

If yes, have Appellants demonstrated unexpected results, that when weighed with the evidence of obviousness, are sufficient to demonstrate the nonobviousness of the anhydrous composition of claim 39?

FINDINGS OF FACT

FF1 The Examiner rejects claims 39-42, 44-62, 64, 66-71, 74, 75, 77-80, and 83 under 35 U.S.C. § 103(a) as being rendered obvious by Sun. (Ans. 3.) As Appellants do not argue the claims separately, we focus our analysis

on claim 39, and claims 40-42, 44-62, 64, 66-71, 74, 75, 77-80, and 83 stand or fall with that claim.

FF2 The Examiner finds that Sun teaches “anhydrous topical preparations with good physical stability and excellent cosmetic attributes comprising propylene carbonate; one or more short chain alcohols and/or glycols, such as ethanol, isopropanol, propylene glycol, polyethylene glycol, etc; glycerol (glycerine); and an active ingredient.” (*Id.*) The Examiner notes that Sun exemplifies ethanol at 55.875% by weight, which the Examiner finds reads on about 50% by weight. (*Id.* at 4.)

FF3 The Examiner finds that Sun also teaches the use of the anti-fungal, ketoconazole as an active agent. (*Id.*) As to the limitation that the composition “does not contain a retinoid or a steroid,” the Examiner notes that Sun exemplifies a composition containing an antifungal, (*i.e.*, miconazole nitrate) that does not contain a steroid or a retinoid. (*Id.* at 6 (citing Sun, col. 10, ll. 30-68).)

FF4 Specifically, Sun

describes entirely anhydrous preparations comprising (I) propylene carbonate, (II) one or more short carbon chain alcohols and glycols including *ethanol*, isopropyl alcohol, *propylene glycol*, butylene glycol, hexylene glycol *polyethylene glycol*, methoxypolyethylene glycol and their derivatives, and (III) either or both of *glycerol* and one or more therapeutically or cosmetically active ingredients.

(Sun, col. 5, ll. 24-31 (emphasis added).)

FF5 Sun teaches that the active agent is preferably an antifungal agent, including miconazole nitrate and ketoconazole. (*Id.* at col. 6, ll. 6-12.)

FF6 Sun teaches further that they “have prepared anhydrous, single phase therapeutic products containing from less than 1 wt % to over 58 wt % of alcohols as cosolvent.” (*Id.* at col. 12, ll. 33-35.)

FF7 The Examiner notes that Sun “does not specifically exemplify the combinations as herein envisioned.” (Ans. 4.)

FF8 The Examiner concludes that it would have been obvious to the ordinary artisan “to provide a composition comprising the glycols and alcohols as herein envisioned because Sun [] teaches that one or more of such glycols and/or alcohols may be used in the anhydrous preparations described therein,” and as Sun “specifically exemplifies combinations of alcohols and/or glycols in the anhydrous preparations.” (*Id.* at 4-5.)

FF9 The Examiner concludes further that it would have been obvious to use ketoconazole as the active agent because Sun teaches that miconazole nitrate and ketoconazole are both antifungal agents and may be used interchangeably. (*Id.* at 5.)

FF10 The Examiner also concludes that it would have been obvious to optimize the concentrations of the components, because such optimization is routine. (*Id.* at 5-6 (citing *Aller*, 220 F.2d at 456).)

FF11 As to the limitation that the composition does not contain a steroid or retinoid, the Examiner concludes that as Sun exemplifies compositions that do not contain a steroid or retinoid, Sun renders obvious the claimed composition that excludes a steroid or retinoid. (Ans. 6.)

FF12 The Declaration of Geert Cauwenbergh compared an anhydrous gel formulation of ketoconazole, referred to as the “the Combination Product,”

to an aqueous product and an anhydrous formulation containing ketoconazole and the steroid desonide. (Cauwenbergh Declaration, ¶13.)

FF13 The “Combination Product” had the following formulation:

“the Combination Product”

Component	Weight %
ketoconazole	2.0000
desonide	0.0500
polyethylene glycol 400	20.0000
propylene glycol	20.0000
glycerin	20.0000
PPG-15 stearyl ether	2.0000
hydroxypropyl cellulose	1.5000
ascorbic acid	0.3000
butylated hydroxytoluene	0.1000
citric acid, monohydrate	0.1000
FD&C Yellow No. 6	0.0013
D&C Yellow No. 10	0.0010
Alcohol 200 proof	(QS) 33.9477
	100.0000

(*Id.*)

PRINCIPLES OF LAW

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The Supreme Court has recently emphasized that “the [obviousness] analysis

need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR Int’l v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *Id.* at 416. An “[e]xpress suggestion to substitute one equivalent for another need not be present to render such substitution obvious.” *In re Fout*, 675 F.2d 297, 301 (CCPA 1982). Moreover, “where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456 (CCPA 1955)

The burden of demonstrating unexpected results rests on the party asserting them. *In re Klosak*, 455 F.2d 1077, 1080 (CCPA 1972). Moreover, a showing of unexpected results must be commensurate in scope with the breadth of the claims. *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983); *see also In re Greenfield*, 571 F.2d 1185, 1189 (CCPA 1978) (“[O]bjective evidence of non-obviousness must be commensurate in scope with the claims.”)

ANALYSIS

Appellants argue:

Sun teaches compositions containing, *inter alia*, one or more short carbon chain alcohols and/or glycols including ethanol, isopropyl alcohol, propylene glycol, butylene glycol, hexylene glycol, polyethylene glycol, methoxypolyethylene glycol and their derivatives (col. 5, lines 25-29 of Sun, emphasis added).

(App. Br. 11.) Thus, Appellants assert, Sun teaches hundreds of compositions, and thus does not render the claimed composition obvious. (*Id.*)

Appellants argue further that exemplary products 1, 2, and 3 of Sun are described as being formulated according to the invention of Sun, but contain a higher amount of ethanol (55.87 wt %) than is required by the claims on appeal. (*Id.*) Thus, Appellants assert, “there is no guidance for a person of ordinary skill in the art to select Appellant’s particular claimed composition from the lists of components described in Sun.” (*Id.*)

Appellants’ arguments are not convincing. Sun describes anhydrous compositions that encompass the claimed composition, and specifically lists all of the components of the composition of claim 39. (*See, e.g.,* FF4 and FF5.) Thus, we agree with the Examiner that the disclosure of Sun renders the composition of claim 39 obvious. In addition, while Sun exemplifies compositions that contain 55.87 wt% ethanol, as noted by the Examiner, claim 39 recites “about 1 to about 50 percent by weight of ethanol,” and Appellants have pointed to no support in the Specification, nor any evidence that the ordinary artisan would read “about 50%” as excluding 55.87 wt% ethanol. Moreover, Sun teaches that compositions were formulated using from less than 1 wt % to over 58 wt % of alcohols as cosolvent, and thus it would have been obvious to optimize the amount of ethanol in the composition.

Appellants assert further that they have shown unexpected results. (App. Br. 11.) Appellants also argue that Sun teaches away from

compositions that do not include a steroidal agent by listing suitable steroidal anti-inflammatory agents that may be included in the composition.

Appellants' showing of unexpected results, when weighed with the evidence as a whole, is not sufficient to demonstrate the non-obviousness of the claimed composition. As noted by the Examiner (*see* Ans. 30-31), the purported unexpected results are not commensurate in scope with the composition of claim 39, as Appellants have only compared a single formulation of the claimed composition, and have not demonstrated by evidence or argument to why the ordinary artisan would find the results to be representative of the full scope of the composition of claim 39. As to Appellants' argument that Sun teaches away from compositions that do not contain a steroid or retinoid, as noted by the Examiner, Sun specifically exemplifies compositions that do not contain a steroid or retinoid. Thus, Sun renders obvious compositions that both contain and do not contain a steroid or retinoid. *See, e.g., KSR*, 550 U.S. at 419 ("What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103.")

As to the remaining rejections over Sun as combined with Kabara or Thornfeldt, Appellants reiterate the arguments made with respect to the rejection over Sun alone. We do not find those arguments convincing for the reasons set forth above.

CONCLUSIONS OF LAW

We conclude that the preponderance of evidence of record supports the Examiner's conclusion that Sun renders the anhydrous composition of claim 39 obvious. We conclude further that Appellants have not demonstrated unexpected results, that when weighed with the evidence of obviousness, are sufficient to demonstrate the nonobviousness of the anhydrous composition of claim 39.

We thus affirm the rejection of claim 39 under 35 U.S.C. § 103(a) as being rendered obvious by Sun. As claims 40-42, 44-62, 64, 66-71, 74, 75, 77-80, and 83 stand or fall with claim 39, we affirm the rejection as to those claims as well. Finally, as Appellants rely on the arguments made with respect to claim 39 as to the other rejections based on Sun, we also affirm the rejections of claims 63, 65, and 72 under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Sun and Kabara; and claims 76, 81, and 82 under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Sun and Thornfeldt.

10TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

alw

GLAXO SMITH KLINE
c/o THE NATH LAW GROUP
112 SOUTH WEST ST.
ALEXANDRIA, VA 22314-2825